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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/394,264 09/10/99 MORTON

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EXAMINER

HM22/0419

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ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/394,264

Applicant(s)

MORTON ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 and 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 3-7 and 18 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The Amendment filed 23 March 2001 (Paper No. 11) in response to the Office Action of 20 September 2000 is acknowledged and has been entered. Claims 29-34 have been added. Claims 1-34 are pending, claims 8-17 and 19-28 are drawn to a non elected invention. Therefore, claims 1-7, 18 and 29-34 and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The office acknowledges the update to the specification.

The rejection of claim 1 as not being clear by what is meant by “naturally occurring allelic variant” **is withdrawn** in view of applicant’s arguments.

The rejection of claim 4 as not being clear by what is meant by “heterologous polypeptide” **is withdrawn** in view of applicant’s amendment.

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention **is withdrawn** in view of applicant’s amendment.

The declaration under 37 CFR 1.132 filed 23 March 2001 is insufficient to overcome the rejection of claims 1, 2 and newly added claims 29-34 based upon the 102(a) reference of

Art Unit: 1648

Robertson et al. Genomics, December 1997 as set forth in the last Office action because: the declaration was not proper because it was not signed by the inventor Nahid Robertson.

The rejection of claims 1, 2 and newly added claims 29-34 under 35 U.S.C. 102(a) as being anticipated by Robertson et al. (Genomics, December 1997) **is maintained** for reasons of record.

The rejection of claims 1, 2 and newly added claims 29-34 under 35 U.S.C. 102(a) or 102(b), depending on the date of public availability, as being anticipated by sequence AF006741 (GenBank/EMBL, direct submission, 4 June 1997) and sequence AF006740 (GenBank/EMBL, direct submission, 4 June 1997) **is maintained** for reasons of record.

The rejection of claim 1 under 35 U.S.C. 102(a) as being anticipated by Heller et al. (PNAS, September 1998) **is withdrawn** in view of applicant's amendment.

The rejection of claim 1 under 35 U.S.C. 102(a) or 102(b), depending on the date of public availability, as being anticipated by sequence AF012252 (GenBank/EMBL, direct submission, 2 July 1997) **is withdrawn** in view of applicant's amendment.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (Genomics 1994) **is withdrawn** in view of applicant's amendment.

Art Unit: 1648

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by VanCoillie et al. (Genomics, March 1997) **is withdrawn** in view of applicant's amendment.

The rejection of claims 1 and 18 under 35 U.S.C. 103(a) as being obvious over Robertson et al. (Genomics 1994) **is withdrawn** in view of applicant's amendment.

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Robetson et al. (Genomics, December 1997) in view of the Pharmacia Catalog (1996) **is maintained** for reasons of record.

The rejection of claims 1 and 3-7 under 35 U.S.C. 103(a) as being unpatentable over VanCoillie et al. (Genomics, March 1997), Robertson et al. (Genomics 1994) or Heller et al. (PNAS, September 1998) each in view of the Pharmacia Catalog (1996) **is withdrawn** in view of applicant's amendment.

New grounds of rejection necessitated by applicant's amendments:

Claims 1, 30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn a naturally occurring allelic variant of SEQ ID:2. and to nucleic acid sequences that share 85% sequence identity with SEQ ID NO: 1, 90 % sequence identity with SEQ ID NO: 3 and to amino acids sequences that share

Art Unit: 1648

85 % with SEQ ID NO: 2. The specification discloses an isolated cDNA sequence, of SEQ ID NO: 3 and SEQ ID NO: 1, which encodes a predictive polypeptide sequence, SEQ ID NO. 2.

The broadly claimed allelic variants and sequences that share a percent sequence similarity could include proteins that are functionally similar. The instant disclosure of a single species of nucleic acid coding for a single polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. Claiming the allelic variants as having biological activity does not overcome the instant written description rejection because neither the art in general nor the specification provide sufficient descriptive information, such as definitive structural or functional features of the claimed polypeptide and its biological activity. It appears that the biological activity of the instantly claimed COCH5B2 is based on homology modeling with the vonWillibrandt factor. Homology modeling without actual verification of biological activity is insufficient to ascribe a particular activity (see Scott et al. Nature Genetics 1999).

There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The structure of these elements is not conventional in the art and a skilled artisan would therefore not recognize from the disclosure that applicant was in possession of the genus of nucleic acids, representing 85 % identity to SEQ ID NO:1 or representing 90% of SEQ ID NO:3 and an amino acid sequence representing 85% sequence identity with SEQ ID NO: 2. Therefore, there is lack of written description in the instant specification for the claimed variants.

Claims 1, 30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

Art Unit: 1648

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn a naturally occurring allelic variant of SEQ ID:2. and to nucleic acid sequences that share 85% sequence identity with SEQ ID NO: 1, 90 % sequence identity with SEQ ID NO: 3 and to amino acids sequences that share 85 % with SEQ ID NO: 2. The specification discloses an isolated cDNA sequence, of SEQ ID NO: 3 and SEQ ID NO: 1, which encodes a predictive polypeptide sequence, SEQ ID NO. 2. The specification, while being enabling for SEQ ID NO 1-3 does not reasonably provide enablement for the other sequences that share a specific percent sequence identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification discloses the identification CHOCH5B2 protein with SEQID No 2 and the corresponding nucleic acid sequence of SEQ ID No 1. It would be undue burden for one of skill in the art to practice the claimed invention in terms of making all the homologous sequences from the disclosed sequences because the specification provides no guidance as to the many different homologous sequences that can be produced. A 85% homology of SEQ ID NO:1 corresponds to a nucleotide difference of 256 nucleotides, similarly a 90% homology of SEQ ID NO: 3 corresponds to a nucleotide difference of 165 nucleotides, while a 85% homology of SEQ ID NO:2 corresponds to an amino acid difference of 82 amino acids. These nucleotide and amino acid substitutions can be arranged contiguously or sparsely at different positions on a sequence. The state of the art is such that it can not predict what substitution will result in significant structural or functional changes. The classic example of structural/functional differences is hemoglobin where a single amino acid substitution due to a single nucleotide

Art Unit: 1648

change has significant consequences on the ability of the mutant hemoglobin to carry oxygen. A second example comes from a bacterial protease (Riffkin et al. Gene Vol. 167, 1995, pp 279-283), here a change in two nucleotides of the protease sequence results in the difference between virulent and benign disease. This small difference does not only result in epitope differences but also results in changes to the thermostability, elastolytic and caseinolytic activity of the protease. There is no guidance in the specification to teach where the sequence should be substituted, and therefore, the functionality of the protein would be unpredictable. Moreover, one of skill in the art would not know which position of the substitution would retain the characteristics of a COCH5B2 without undergoing extensive experimentation. Therefore, the instant specification is not enabled for the scope of the claims.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "at least one COCH5B2 activity".

Claims 3-7 and 18 objected to because of the following informalities: They are dependent on a rejected claim. Appropriate correction is required.

Conclusion

Claims 1, 2 and 29-34 are rejected.

Claims 3-7 and 18 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Note: A response to the final rejection should include cancellation of the non-elected claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.


JEFFREY STUCKER
PRIMARY EXAMINER